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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,809

07/15/2003

Donna L. Livant

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MEDLEN & CARROLL, LLP  
Suite 350  
101 Howard Street  
San Francisco, CA 94105

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/619,809

Applicant(s)

LIVANT, DONNA L.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/8/05 & 10/27/06.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,9,17,19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,11,13,16 and 23 is/are rejected.
- 7) ☒ Claim(s) 2,3,6,8,10,12,14,15,18,20,22 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 8/8/05 wherein the specification was amended and claims 6, 8, 10, 12, 18, 20, 22, and 24 were amended.

**Note:** Claims 1-24 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to a method for treating a wound comprising administering an MMP prodomain peptide to a subject having at least one wound.

## **RESPONSE TO APPLICANT'S ELECTION**

3. The Examiner acknowledges receipt of Applicant's election with traversal of the species MMP1 (Ac-PRCGVPDVAQF-NH<sub>2</sub>) in the response filed 10/27/06. The traversal is on the ground that the MMP peptides are structurally related and the Examiner has not shown an undue search burden.

Applicant's arguments are not found persuasive because the species are distinct. For example, while the sequences disclose in claims 6, 8, 10 and 12 contain some overlapping amino acid residues, the entire sequences are not obvious over one another because of the substitutions of the various amino acid residues at various positions. Furthermore, Applicant's attention is directed to the cited prior art below which renders obvious peptides derived from MMP-9. However, review of the reference does not disclose the sequences of claims 6, 8, 10, and 12. Thus, the election of species requirement is deemed proper and is made FINAL.

**Note:** Initially, Applicant's elected species (the species of claim 6) was searched. However, since no prior art was found, the search was expanded to the peptides having the sequence of claims 8, 10, and 12. Thus, since no prior art was found for the species of claims 8, 10, and 12, the search was expanded to a peptide derived from MMP9 (see claim 11). Therefore, since prior art was found for a peptide derived from MMP9, the search was not further expanded.

#### **WITHDRAWN CLAIMS**

4. Claims 5, 7, 9, 17, 19, and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **112 REJECTIONS**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 11, 13, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11, 13, and 23: The claims as written are ambiguous because of the term 'derived from MMP9' (see, for example, claims 11 and 23). In particular, the term 'derived' means 'to produce or obtain (a compound) from another substance by a chemical reaction. The term 'peptide' means 'a natural or synthetic compound containing two or more amino acids linked by the carboxyl group of one amino acid and

the amino group of another'. Thus, it is unclear what peptide Applicant is claiming that is compatible with the instant invention since a peptide may have only two amino acids.

## 102 REJECTIONS

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (Developmental Dynamics, 1999, Vol. 216, No. 1, pages 2-9).

**Yang et al** disclose the expression of MMP-9 and related matrix metalloproteinase genes during axolotl limb regeneration. The spatial and temporal expression of MMP-9 has been analyzed during axolotl limb regeneration. The first phase begins at 2 hours after amputation and expression is confined to the healed wound epithelium. This phase continues for 2 days, showing peak expression at 14 hours after amputation. The second phase begins a few days later when a small blastema has formed. During this phase, expression is in the mesenchyme, localized to cells around the tips of the cut skeletal elements. This expression is maintained through several stages until redifferentiation begins. The timing and position of the second phase of expression is consistent with a role for MMP-9 in the removal of damaged cartilage matrix (see entire document, especially, abstract; page 4, Figure 2; page 4, 'MMP-9 Expression'; and page 5, Figure 3). Thus, both Yang et al and Applicant

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disclose a method of treating a wound by administering an MMP prodomain peptide derived from MMP-9.

### 103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13, 16, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (Developmental Dynamics, 1999, Vol. 216, No. 1, pages 2-9).

**Yang et al** (see discussion above) fail to disclose a kit comprising a peptide derived from MMP-9. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit containing a peptide derived from MMP-9 because of the ever present need for such kits in hospitals, clinics, or other medical facilities. In addition, a skilled artisan would be able to apply the procedures for generating diagnostic and therapeutic kits found in Fritzberg et al (US Patent No. 5,175,343, see column 16, line 37 through column 25, line 44).

### CLAIM OBJECTION

11. Claims 2, 3, 6, 8, 10, 12, 14, 15, 18, 20, 22, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in


independent form including all of the limitations of the base claim and any intervening claims.

**Note:** The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of treating a wound as set forth in independent claim 1 wherein one of the amino acid sequences as set forth in independent claims 6, 8, 10, 12, 18, 20, 22, and 24 are disclosed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
D. L. Jones  
Primary Examiner  
Art Unit 1618

January 18, 2007